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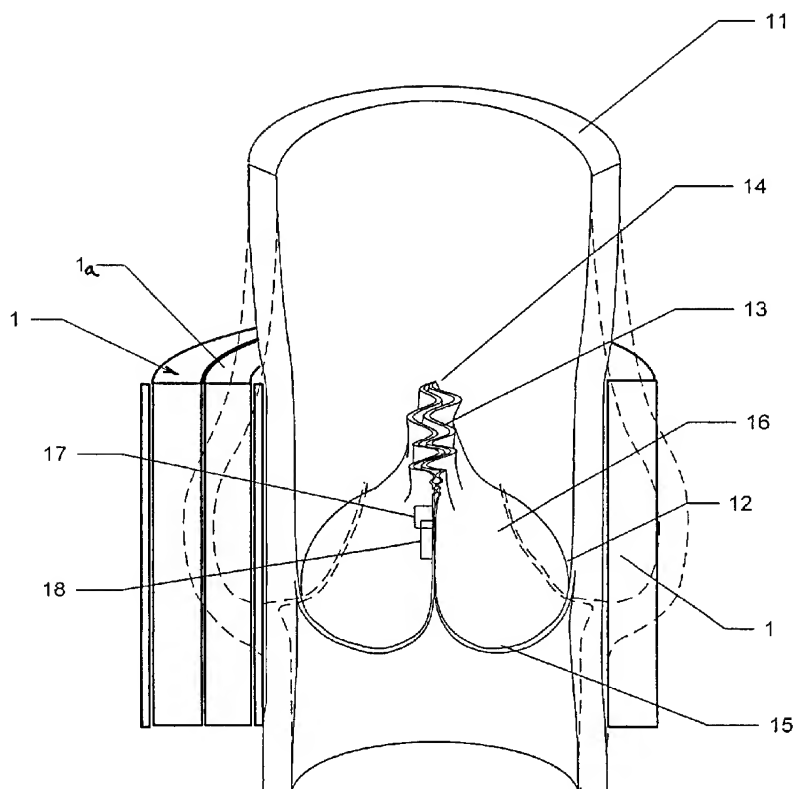
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(54) Title: IMPROVEMENTS IN DESIGN OF EXTERNAL VENOUS VALVE STENTS FOR THE CORRECTION OF INCOMPETENT VENOUS VALVES



(57) Abstract: Improvements to external stents to render incompetent venous valves competent are disclosed. The device is an inelastic bio-compatible cuff (1) that encircles the venous valve cusps (15) decreasing the internal diameter of the vein wall (11) to allow apposition of the cusps (15) and create competence. The improvements over previous designs include the addition of calibrated known diameters to create competence for different phenotypes. The different diameters are indicated by holes (2, 3, 4) in the body (1). The buckle attachment (6) allows the body of the device to become conical or inverted to become pyramidal as appropriate. The buckle (5) is wider than prior art designs to allow the device to become elliptical at smaller diameters. The angle of the notches (10) in the device are approximately 15° to allow better overriding at the sapheno-femoral junction which allowing for better competence of the valve.

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IMPROVEMENTS IN DESIGN OF EXTERNAL VENOUS VALVE STENTS
FOR THE CORRECTION OF INCOMPETENT VENOUS VALVES

FIELD OF INVENTION

This invention relates to the correction of incompetent venous valves.

5 BACKGROUND OF THE INVENTION

Venous valves in mammals are usually bicuspid valves, with each cusp forming a sack or reservoir for blood which, under pressure, forces the free edges of the cusps together to prevent retrograde flow of the blood and allow only antegrade flow to the heart. When an incompetent valve attempts to close
10 in response to a pressure gradient across the valve, the cusps do not seal properly and retrograde flow of blood occurs.

There are two chronic venous diseases in which incompetence of venous valves is thought to be an important factor in the pathophysiology. These are varicose veins and chronic deep venous insufficiency.

15 The varicose vein condition consists of dilatation and tortuosity of the superficial veins of the lower limb and resulting cosmetic impairment, pain and ulceration. Primary varicose veins are the result of primary incompetence of the venous valves separating the superficial venous system from the deep venous system. Secondary varicose veins occur as the result of deep venous
20 hypertension which has damaged the valves of the perforating veins.

Chronic deep venous insufficiency consists of deep hypertension of the lower limb with associated pigmentation, pain, swelling, ulceration and varicose veins.

25 For the sake of convenience, the invention will be described in relation to the correction of incompetent valves in the venous system of the lower limb in man, but, it is to be understood that the invention is not limited thereto.

The venous system of the lower limb consists essentially of the superficial venous system and the deep venous system. The superficial system includes the great saphenous vein and the small saphenous vein. The

deep venous system includes the anterior and posterior tibial veins which unite to form the popliteal vein which in turn becomes the femoral vein when joined by the small saphenous vein.

5 The initial defect in primary varicose veins often involves localised incompetence of a venous valve thus allowing reflux of blood from the deep venous system to the superficial venous system. This incompetence is traditionally thought to arise at the saphenofemoral junction but may also start at the perforators. Thus, gross saphenofemoral valvular dysfunction may be present in even mild varicose veins with competent distal veins. Even in the
10 presence of incompetent perforators, occlusion of the saphenofemoral junction usually normalises venous pressure.

The initial defect in secondary varicose veins is often incompetence of a venous valve secondary to hypertension in the deep venous system. Since this increased pressure is manifested at many points, correction of one site of
15 incompetence could clearly be insufficient as other sites of incompetence will be prone to develop. Apart from the initial defect, the pathophysiology is similar to that of varicose veins.

Once the initial incompetence occurs, incompetence in other valves in the system will tend to occur secondary to the venous hypertension.

20 Dilatation of the vein wall, whether idiopathic (primary varicose veins) leads to valvular incompetence. This dilatation may eventually lead to stretching and sclerosis of the valve. Other valves in the system will tend to become incompetent as the reflux of blood causes dilatation of the vein wall. We have found that it is possible to reverse or prevent the destructive process
25 by overcoming this dilatation. Even if the vein wall weakness is generalised as appears to be the case with primary varicose veins, correction of the initial defect will delay or prevent stress being placed on that wall and thus hinder progression of the disease.

BACKGROUND ART

In the main, prior art approaches to restoring competency of incompetent valves has involved venous reconstruction surgery of three basic kinds, namely, venous valve transplants, venous transposition and venous
5 valvuloplasty.

As the term implies, the venous valve transplant approach involves the replacement of the segment of the vein having the incompetent valve with a segment of another vein having a competent valve. The venous transposition approach involves the redirection of the venous system so as to bypass an
10 incompetent valve and venous valvuloplasty involves venous valve reconstructive surgery in which the free length of the valve cusps is reduced by plicating sutures.

These approaches to the prior art are well documented in A RATIONAL
APPROACH TO SURGERY OF THE CHRONIC VENOUS STASIS
15 SYNDROME by Harry Schanzer AND E Converse Peirce ANNUALS OF
SURGERY 1982, 195: 25 - 29 as well as in VALVULOPLASTY AND VALVE
TRANSFER by Seshadri Raju Inter. Angio. 4 1985 419-424.

A single example on one patient of an experimental technique for treating an incompetent venous valve not involving the above types of venous
20 surgery is described in an article by Dag Hallberg in ACTA CHIR SCAND 138: 143-145, 1972. Hallberg placed a band two or three millimetres larger than the diameter of the vein around the vein.

The band was made of DACRON™ polyester and polyester and was applied when the patient was in the horizontal position. The band was retained
25 loosely in position by several sutures in the venous adventitia.

Hallberg's method could not restore competence to the majority of the incompetent venous valves. In patients with venous disease, incompetent valves will usually be incompetent in the horizontal as well as the vertical positions. See, for example, FEMORAL VEIN RECONSTRUCTION IN THE

MANAGEMENT OF CHRONIC VENOUS INSUFFICIENCY by Ferias EBB. and Chastener R., ARCHIVES OF SURGERY, 1982, 117:1571 - 1579.

5 Ferias and Chastener operated on 53 femoral veins in which the valves had been demonstrated pre-operatively to be incompetent. In only one case was the valve noted to be competent when the patient was horizontal at the time of operation. Chastener's approach was to suture the vein to prevent post-operative dilatation.

10 It is well known that by itself DACRON™ polyester material causes marked fibrosis as well as foreign body reaction. Therefore, DACRON™ polyester cannot alone be considered biocompatible. In fact, DACRON™ polyester has been employed to stimulate fibrotic reactions which incorporate the synthetic fabric into tissue (see: S. Raju, ANN. SURG. (1983) 197, 688-697).

15 The article REVASCULATION OF SEVERELY ISCHEMIC EXTREMITIES WITH AN ARTERIOVENOUS FISTULA by F.W. Blaisdell et al in AMERICAN JOURNAL OF SURGERY, Volume 112, pages 166-173 discloses problems associated with the use of DACRON™ polyester as an implantable material. In a number of cases, gradual narrowing of arteriovenous fistulas under a woven DACRON™ polyester sleeve was demonstrated.

20

 In physical terms, the Hallberg approach was a static one. Once the cuff was sutured into position, no attempt was made to reduce the diameter of the vein at the valve site to restore competency of the valve. Indeed, Hallberg's single patient experiment was concerned with further dilatation of the vein at the valve site rather than reduction in the diameter of the dilated valve to restore competency.

25

 Reference is also made to published PCT application entitled "Correction of Incompetent Venous Valves" (International Application No. PCT/AU87/0021, International Publication No. WO 88/00454.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

In order that the invention may be more readily understood and put into practical effect, reference will now be made to the accompanying drawings in which:

- 5 Fig. 1(a) illustrates a top plan view of a right sapheno - femoral design;
 Fig. 1(b) illustrates a top plan view of an unnotched design for deep valve repair or valves along the length of the long saphenous system;
 Fig. 1(c) illustrates a top plan view of a design for the left sapheno-femoral junction;
- 10 Fig. 1(d) illustrates the device of figure 1(c) in side view;
 Fig. 1(e) illustrates the device of figure 1(d) in end view;
 Fig. 2 illustrates in isometric perspective, a valve cuff assembled so that the cranial diameter is greater than the caudal diameter;
- Fig. 3(a) is a cross section perspective view of an incompetent venous
15 valve;
 Fig. 3(b) is a perspective view, of a partially cross sectioned of a venous valve after cuff application; and
 Fig. 4 is a cross section through a cuff and valve.

20 BEST MODE AND OTHER EMBODIMENTS OF THE INVENTION

 The invention describes a cuff 1 for restoring competence to an incompetent venous valve consisting of a textile or woven textile and polymer composite such as an inelastic DACRON™ and silicone external stent that has very little elasticity. The DACRON™ and silicone composite has some
25 shape memory which is useful in resisting the compressive forces exerted by the skin near the cuff which tend to collapse the valve after wound closure. The stent is applied to the circumference of the venous valve to change the internal diameter of the venous valve ring and prevent the upward and lateral motion of the venous valve sinus.

The diameter of the cuff must be variable and the superficial venous system in a human can vary from 3mm to 8mm. The change in diameter of the device must be continuously variable so that it can be changed as the valve is tested. In order to continuously vary the cuff's diameter, the cuff is initially
5 provided as an elongated strap or body 1a which terminates in a buckle 5. Both the strap 1a and the buckle 5 are fabricated from a woven DACRON™ fabric which is coated with a silicon rubber compound. As shown in figure 1(e) the buckle 5 surrounds the strap 1 and is bonded or affixed to the strap so that there remains a buckle opening 20 through which the tapered tip 21 of the
10 strap can pass. In practice and as shown in Figures 2 and 4, the incompetent valve is buckled into the cuff, whereupon the diameter is fixed via stapling or suturing to the vein wall.

Often during dissection, the smooth muscle in the venous wall will create a spasm which decreases the amount of incompetence. This tends to
15 cause the operator to leave the cuff diameter too large and when the spasm ceases, incompetence in the long term persists despite the valve being competent at first.

For repairing of the sapheno-femoral junction, data has now been accumulated to indicate that the diameter for the smaller female is
20 approximately 5.5mm which equates to an internal diameter of 4.5mm allowing for the thickness of the vein wall at the sapheno-femoral junction itself. There are three centrally located holes 2, 3 and 4 in the body of the cuff 1. These represent calibrations to internal diameters of 4.5mm, 5.5mm and 6.5mm when the leading edge of the buckle 22 is brought into registry with that part of a
25 particular hole which is closest to the tip 21. These three holes equate with internal diameters for a small female at 4.5mm, an average female at 5.5mm and a male at 6.5mm.

There are three principal embodiments. Figure 1(a) shows the design 7 for the right sapheno-femoral junction or similar tributaries entering the deep

systems. In this design, the notch 10 is located near the buckle 5 and along the left edge of the strap 1 in top plan view. Figure 1(b) shows the unnotched cuff 8 for deep valve repair or valves along the length of the long saphenous system. Figure 1(c) shows the design 9 for the left sapheno-femoral junction.

5 The longitudinal shape of the cuff must be conical if necessary, i.e. the cranial diameter needs to be greater than the caudal diameter and this is shown in Figure 2. The reasoning behind this design modification comes with a better understanding of venous valve closure. Essentially these facts have been derived through the use of Venoscope. The descending mass of blood
10 creates a downward force on the venous cusps which rotate laterally and upwards compelling the cusps to slam together creating competence. In venous disease the free edges of the valve cusps become floppy and stretch and the valve ring dilates. By allowing the cuff to become conical, (larger end up) the tendency for the upward outward motion of the cusps is minimised
15 therefore minimising the tendency to prolapse as seen in Figure 3. This improvement in function is made possible by lengthening the buckle 5. Thus, the buckle's sides 6 are slightly longer than would be required if the belt were always at a right angle to the strap 1a. This looseness in the buckle 5 allows the strap 1a to be misaligned slightly so as to allow the cuff to form a cone.
20 This improvement also allows the reverse to occur i.e. the cuff can be made to be pyramidal (larger end down) in shape. As a result the cuff can be used in some congenital abnormalities of determination of the long saphenous vein. When a double long saphenous system terminates, the join is immediately before the terminal valve at the sapheno-femoral junction. The only way to
25 make the valve competent is to make the caudal diameter less than the cranial diameter. By lengthening the attachments 6 of the buckle 5 to the body of the cuff 1 then the cuff becomes pyramidal. This can then be sutured in place.

At the sapheno-femoral junction, the venous valves are disposed longitudinally to the skin. Competence is shown to be better achieved if the

external valve rings are elliptical in the cross-sectional axis. This is achieved by widening the buckle 5 so that the top of the superficial aspect is flattened. Posterior flattening is achieved by the cuff coming into contact with the common femoral vein or its surrounding adventitia. The reverse is true for the deep venous valve cusps. For repair in the popliteal and tibial systems they are disposed 90° to the skin and therefore the buckle 5 has to be disposed directly on the side wall of the deep vein. The buckle 5 has therefore been increased to accommodate these elliptical changes at smaller diameters (figure 4).

Another feature that creates and improves competence at the sapheno-femoral junction is that the notch 10 at the superior portion of the cuff has been modified. This allows high riding valve *cusps to be encircled and therefore their diameter decreased. The notch has a depth d (see Fig 1(c)) which is half the width of the strap 1a. The sides of the notch 10 are curved to define the arc of a circle. The prior art notch was set at 45° of arc and this has now been amended to 15°. This allows for better fixation of the cuff to the common femoral vein and therefore avoids bulging of the sapheno-femoral junction above the device.

CLAIMS

1. A variable diameter cuff for restoring competence to an incompetent venous valve comprising:-
- 5 an elongated strap which terminates in a buckle;
the strap having a tapered end;
the buckle defining a buckle opening through which the end can pass;
the strap and the buckle formed from a textile and polymer composite.
- 10 2. The cuff of claim 1, wherein:-
the strap further comprises one or more centrally located holes which aid in calibration of the diameter.
- 15 3. The cuff of claim 1, wherein:-
the holes are three in number.
4. The cuff of claim 2, wherein:-
there are at least three holes; and
20 there are holes designating diameters of 4.5, 5.5 and 6.5mm.
5. The cuff of claim 1, further comprising:-
a notch located near the buckle.
- 25 6. The cuff of claim 1, wherein:-
the buckle has sides slightly longer than the width of the strap so that the cuff may assume a conical shape when in use.
7. The cuff of claim 1, wherein:-

the buckle and cuff are formed from the same composite material.

8. The cuff of claim 7, wherein:-

5 the material is a DACRON™ and silicone composite with some shape memory and very little elasticity.

9. The cuff of claim 1, wherein:-

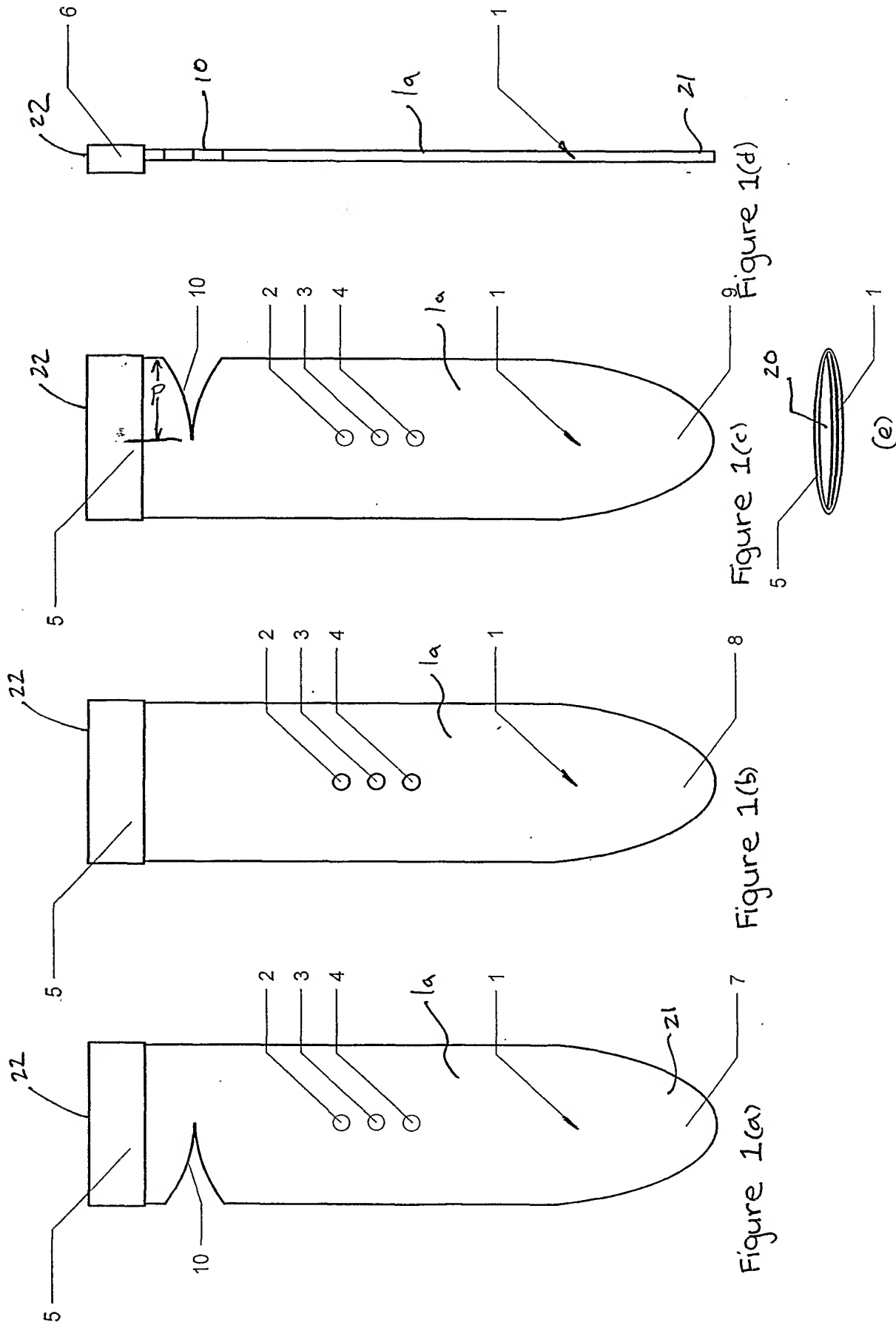
10 the buckle has a width which allows flattening of the top of the superficial aspect.

10. The cuff of claim 5, wherein:-

the notch has sides which are curved.

11. The cuff of claim 5, wherein:-

15 the curved sides form an arch defining about 15° of arc.



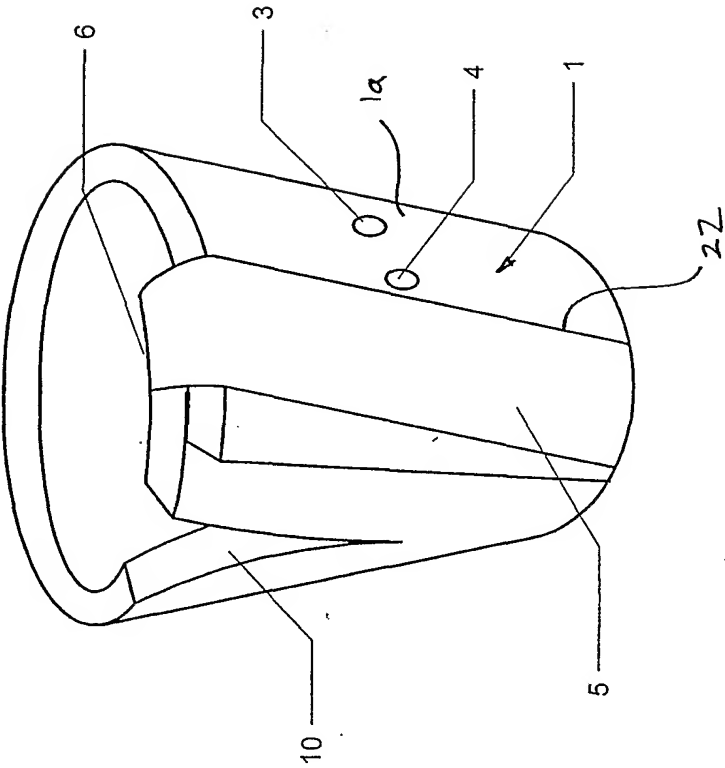


Figure 2

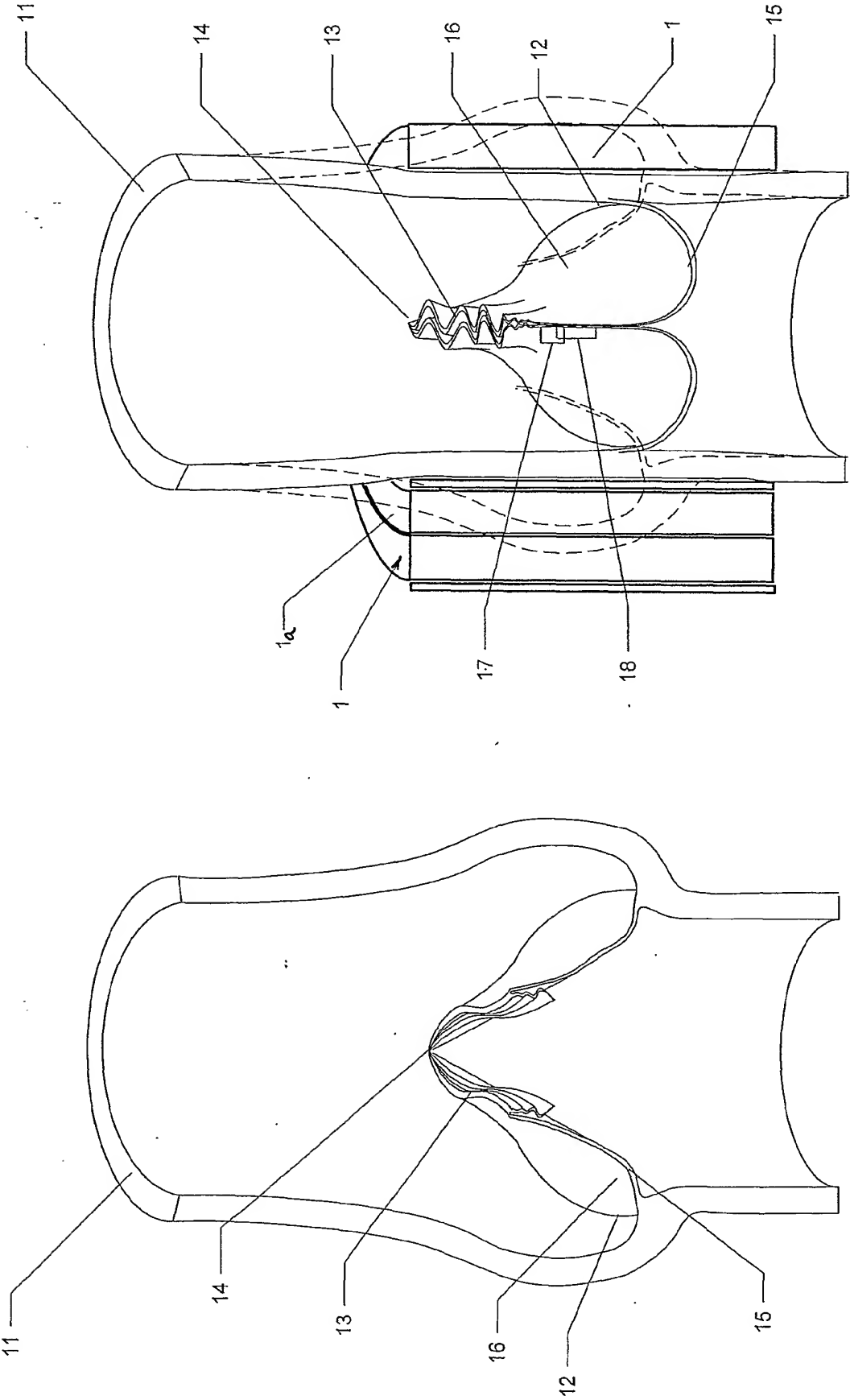


Figure 3(b)

Figure 3(a)

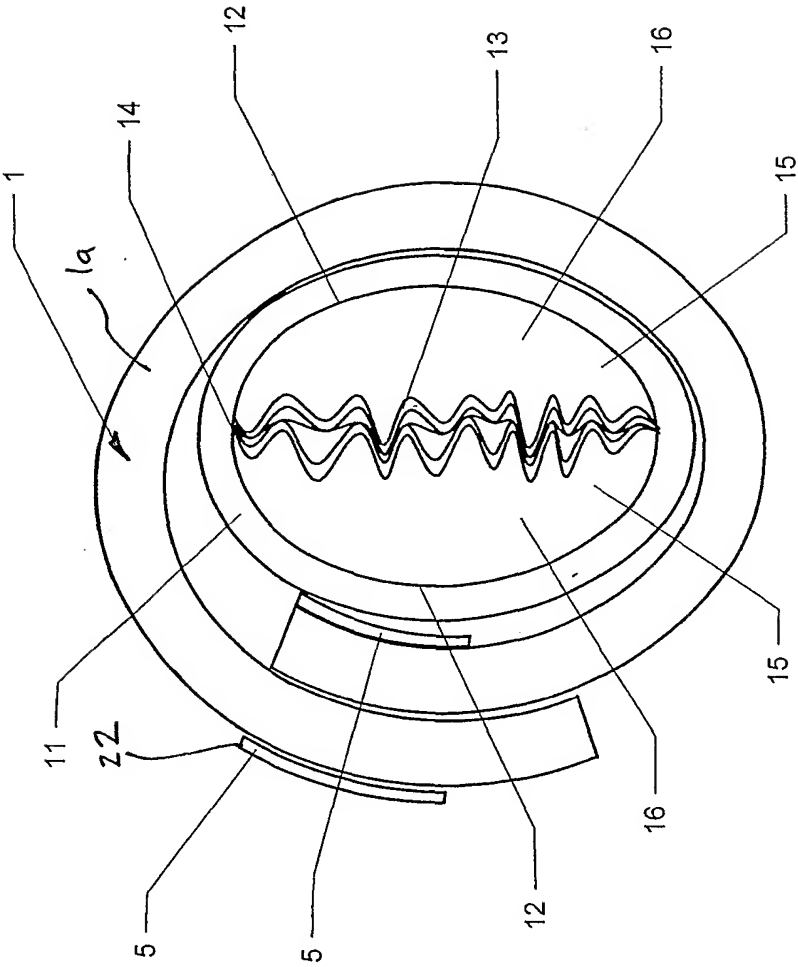


Figure 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU02/00361

A. CLASSIFICATION OF SUBJECT MATTERInt. Cl. ⁷: A61B 17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

SEE ELECTRONIC DATA REFERENCE BELOW

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI + keywords: venous vein arter valve strap cuff collar buckle clasp clamp and similar words

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	WO 88/00454 A1 (QUOTIDIAN NO 100 PTY LTD) 28 January 1988 Pages 10-18	1, 5, 6, 8
A	WO 97/40755 A1 (W L GORE & ASSOCIATES INC) 6 November 1997 Pages 6-10	
A	WO 88/06021 A1 (VASO PRODUCTS AUSTRALIA PTY LTD) 25 August 1988	

☐ Further documents are listed in the continuation of Box C
 ☒ See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU02/00361

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	8800454	AU	77068/87	CA	1324461	EP	276254
		US	5147389	US	4904254		
WO	9740755	AU	28170/97	CA	2252894	EP	898463
WO	8806021	AU	13440/88	CA	1322314	EP	302093
		US	5211649				
							END OF ANNEX